K091096

510(K) SUMMARY
NaturaZ Series

JUN 18 2009

This 510(k) summary of safety and effectiveness for NaturaZ Series (B16, B20, B42, B60, B98, B100) material is submitted in accordance under Part 21 CFR 807.92.

APPLICANT: The Dental Solution, Inc.

ADDRESS: Geum Cheon Gu, Ga San Dong, 371-36
4th Floor S&T Building
Seoul, Korea 153-803

MANUFACTURER: DMAX Co., LTD
Geum Cheon Gu, Ga San Dong, 371-36
4th Floor S&T Building
Seoul, Korea 153-803

CONTACT PERSON: Andrew Paeng, Consultant

TELEPHONE: (310) 858-2900, FAX (615) 712-7724

DEVICE NAME: NATURAZ SERIES (B16, B20, B42, B60, B98, B100)

COMMON NAME: Porcelain, Powder for clinical use

CLASSIFICATION: Porcelain, Powder for clinical use
21 CFR 872.6660
Class II
Product Code: EIH
Panel: 76 (Dental)

PREDICATE DEVICE: KaVo Everest® ZS-Blank K032081

DEVICE DESCRIPTION:
NaturaZ Series is a pre-formed material for use by dental laboratories in filling orders/prescriptions for dental prosthetics

INDICATION: NaturaZ Series is used inthe manufacture of dental prosthetics. The Dental Solution, Inc. proposes that the materials distributed within the United States be labeled:

"CAUTION: Federal (US) law restricts the sale of this device to, or on the order of, licensed professionals."

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PERFORMANCE DATA: Non Required. The claim of substantial equivalence is based on comparisons of formulations and intended uses of the predicate device, KaVo Everest ZS-Blank.

CONCLUSION: There are no significant differences between the NaturaZ Series and the predicate device. Therefore, NaturaZ Series are equally safe and effective than the predicate device, KaVo Everest ZS-Blank.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

The Dental Solution, Incorporated
C/O Mr. Andrew Paeng
Consultant
The Dental Solution America, Incorporated
9301 Wilshire Boulevard PH5
Beverly Hills, California 90210

Re: K091096
Trade/Device Name: NaturaZ Series B16, B20, B42, B60, B98, B100
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 15, 2009
Received: April 16, 2009

Dear Mr. Paeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

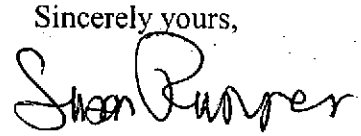
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION OF USE

510(k) Number: _____

DEVICE NAME: NaturaZ Series B16, B20, B42, B60, B98, B100

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Prescription Use X		Over-The-Counter Use _____
(21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulley for MSE

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091096
